REMARKS

In the Office Action, Claims 1, 2, 6-10, 12, 32, 37-41, 43, 94, 95, 108-109, 114-115 were examined. Of these Claims, Claims 6-10, 38, 41, 94, 95, and 108 have been canceled. Claims 1, 2, 12, 32, 37, 39, 40, 114 and 115 have been amended, and Claim 116 has been added. Support for new Claim 116 can be found in Claim 40, as originally filed. As a result of the amendments, Claims 1, 2, 12, 32, 37, 39, 40, and 114-116 are presented for examination.

Withdrawn Claims

Withdrawn Claims 3-5, 11, 13-31, 34-36, 42, 44-62, 92, 93, 96-107 and 110-113 have also been canceled herein. The remaining withdrawn claim, Claim 33 has been retained as a claim dependent on a generic claim. Accordingly, upon allowance of the generic claim, consideration of Claim 33 is respectfully requested.

Claim Objections

The Examiner has maintained the objection to Claim 41 for lack of antecedent basis for recitation of "related microorganisms". The Applicants have now amended claim 41 to remove this language rendering the objection moot.

Claim rejections under 35 U.S.C. §112

The Examiner has maintained the rejection of Claim 41 under 35 U.S.C §112, first paragraph, as containing new matter. This claim has now been canceled, and the rejection is moot.

The Examiner has maintained the rejection of Claims 1, 2, 6-10, 12, 32, 37-41, 43, 94, 95, 108, 109, 114 and 115 under 35 U.S.C §112, first paragraph, as being non-enabled. In the Office Action of May 30, 2002 (Paper No. 22), paragraph 32, lines 1-4, the Examiner stated that the specification was "enabling for . . . a composition comprising an isolated polypeptide of the amino acid sequence of SEQ ID NO:2 and a pharmaceutically acceptable carrier." The claims have now been amended to recite such a composition. Accordingly, the Examiner has already

agreed that such claims are enabled by the specification, and withdrawal of the rejection is respectfully requested.

The Examiner has maintained the rejection of Claims 41, 43 and 109 under 35 U.S.C §112, first paragraph, as being non-enabled. These claims have now been canceled, and the rejection is moot.

The Examiner has maintained the rejection of Claims 1, 32 and 41 under 35 U.S.C §112, second paragraph, as being indefinite. More specifically, the Examiner has maintained that these claims are vague and indefinite in the recitation of "an isolate or sub-type of *L. intracellularis*", because it is unclear what the limitation represents. However, Applicants have amended Claim 1 to remove any reference to isolates, sub-types and subspecies and Claim 41 has been canceled. Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has maintained the rejection of Claims 2, 6-9, 37-40, 43, 109, 114 and 115 under 35 U.S.C §112, second paragraph, as being indefinite for being dependent on base claims 1, 32, and 41 considered vague and indefinite by the Examiner. However, in view of the comments in the preceding paragraph, this rejection is no longer applicable.

The Examiner has rejected Claims 1, 2, 6-9, 32, 37-40, 114 and 115 under 35 U.S.C §112, second paragraph, as being indefinite for a variety of reasons. More specifically:

(a) Claim 94 was rejected for reciting "said related microorganism" with no antecedent basis for "said". Claim 94 has been canceled, and this rejection is now moot.

(b) Claims 1, 6-8, 32, 94 and 95 were rejected for reciting "sub-type of *L. intacellularis*", as the Examiner did not see the difference between "sub-type" and "isolate". The claims have been amended to remove the language "sub-type" and/or "isolate" so this rejection is no longer applicable.

(c) Claim 9 was rejected for recitation "wherein said protein is ... glucarate trasporter", as the origin of such protein is unclear. Claim 9 has been canceled, and the rejection is now moot.

(d) Claim 115 was rejected for lack of antecedent basis for recitation of "said peptide". The Applicants have amended Claim 115 and removed the reference to "said peptide" so that this rejection is no longer applicable.

(e) Claim 9 was rejected for reciting an improper Markush group. Claim 9 was canceled and this rejection is moot.

(f) Claim 40 was rejected for reciting an improper Markush group. The Applicants have amended Claim 40 to now recite a proper Markush group in order to overcome this rejection.

(g) Claims 2, 6-9, 37-40, 114 and 115 were rejected as being dependent on independent claims 1, 32 and 41 rejected under 35 U.S.C §112, second paragraph, as being indefinite. Because claims 1, 32 and 41 have been amended to be definite, the dependent claims are now definite.

Rejections under 35 U.S.C. §102

The Examiner has maintained the rejections of Claims 1 and 2 under 35 U.S.C. §102(e) as being anticipated by Knittel *et al.* (US 5,714,375) as evidenced by Lemarchand *et al.* (Vet. Pathol. 34:152-156, March 1997, abstr.). More specifically, the Examiner has maintained that Knittel *et al.* did teach an isolated, partially purified antigen of *L. intracellularis* that has been passed through a 22 gauge needle, centrifuged to remove cellular nuclear debris and resuspended in a desired diluent, and asserted that such an antigen would be inherently immunogenic as evidenced by Lemarchand *et al.*

However, Claim 1 has been amended to specifically recite a protein "having an amino acid sequence comprising SEQ ID NO:2." To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. Knittel *et al.* teaches only an attenuated form of L. intracellularis and that the attenuated L. intracellularis can be used as an antigen. Thus, the term "antigen" in this reference refers only to the whole cell -not to a purified component of that cell. This can be seen in column 8, lines 11-17 which states that "The IS intracellularis bacteria grown according to the method of the instant invention can be used as an antigen in an ELISA...". Further in column 16, line 49-57, the method of purification of the "antigen" is shown which involves simply centrifuging the Tissue culture cells that the IS intracellularis bacteria was growing in, lysing the cells by passing through a large gauge needle, and removing the cellular components such as nuclei by centrifugation. Further, Knittel et al

does not teach or suggest the use of any heatshock protein, much less one comprising a sequence of SEQ ID NO:2, or that such a ptotein would be useful to induce an immune response. This method would simply purify the bacterial cells (note that bacterial cells do not have nuclei) and would not lyse them. Thus, Knittel et al. does not teach or suggest a composition comprising an isolated heatshock protein and Applicants respectfully request withdrawal of the rejection of Claims 1 and 2 under 35 U.S.C. §102(e) over Knittel *et al.* (US 5,714,375).

The Examiner has rejected Claims 1 and 2 under 35 U.S.C. §102(a) as being anticipated by McOrist *et al.*, 1995 (Int. J. Syst. Bacteriol. 45:820-825, 1995). More specifically, the Examiner believes that McOrist *et al.* 1995 taught an isolated and purified Lawsonia intracellularis (IS intracellularis)-specific DNA and several sarkosyl soluble proteins isolated therefrom following sonicating of whole cells, which the Examiner considered intrinsically immunogenic. However, Even if McOrist *et al.* does teach Sarkosyl soluble proteins, McOrist does not teach any heatshock proteins, much less a protein having a sequence comprising SEQ ID NO:2., as claimed in amended Claim 1. Thus, McOrist does not teach the use of the protein recited in Claim 1. Therefore, the Applicants respectfully request withdrawal of the rejection of Claims 1 and 2 under 35 U.S.C. §102(a) over McOrist *et al.*, 1995.

The Examiner has rejected Claims 1 and 2 under 35 U.S.C. §102(b) as being anticipated by McOrist *et al.*, 1989 (Infect. Immun. 57:957-962, 1989). More specifically, the Examiner believes that McOrist *et al.*, 1989 taught outer membrane preparations of an intracellular *Campylobacter*-like microorganism associated with Porcine Proliferative Enteropathies containing two major proteins and several minor proteins, some of which were recognized by monoclonal antibodies specific to the *Campylobacter*-like microorganism obtained from proliferative enteritis lesions. Such proteins are intrinsically immunogenic. However, McOrist *et al.* 1989 does not teach the use of the protein recited in Claim 1. Therefore, the Applicants respectfully request withdrawal of the rejection of Claims 1 and 2 under 35 U.S.C. §102(a) over McOrist *et al.*, 1995.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned at one of the telephone numbers indicated below to discuss such issues.

Respectfully submitted,

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Dated: 20 Nov. 2003

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